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Sunstein Kann Murphy & Timbers LLP 125 SUMMER STREET BOSTON, MA 02110-1618			CWERN, JONATHAN	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/23/10 has been entered.

### ***Claim Objections***

Claims 127-131 and 143-147 are objected to because of the following informalities:

In claims 127 and 143, the term "a three-dimensional model" should be changed to "said three-dimensional model" as the term is now in the independent claims. Also, these claims appear to be redundant now in view of the addition to the independent claims and do not appear to present a further step in the method.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 7, 10, 15, 153, and 190 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ateshian et al. (US 6126690) in view of Aouni-Ateshian et al. (US 6161080).

Ateshian et al. disclose an anatomically correct prosthesis and method and apparatus for manufacturing prosthesis. Ateshian show obtaining image data of the surface of a joint, modifying the image data to provide a more functional surface topography, and the fabricating a joint prosthesis. Also, image data of a healthy joint can be obtained and used to fabricate a prosthesis for a similar diseased joint (column 6, lines 20-32). The prosthesis is composed of head surfaces with each surface having an anatomically accurate shape (column 5, lines 35-40). Furthermore, the image data can be obtained by MRI, CT, or stereophotogrammetry methods (column 7, lines 20-39; column 11, line 20-column 12, line 57). These imaging techniques will obtain data of the joint, such as cartilage and subchondral bone properties. However Ateshian et al.

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fail to explicitly describe using cartilage data to aid in the implant construction, analyzing degenerative cartilage in the patient, and estimating gait.

Aouni-Ateshian et al. disclose a method of generating a three-dimensional representation of one or more anatomical joints. Aouni-Ateshian et al. teach that cartilage topography and thickness can be reconstructed, and geometric data needed for a model can be obtained (column 37, line 65-column 8, line 25). Also, that such a model can be used for designing prostheses (column 1, lines 59-65).

When designing a model to analyze an object, it is typical to design the model as close to the real object as possible, in order to accurately analyze what would happen to the real object. Therefore, it is obvious that the physical model would reflect the patient's anatomy, such as the geometry and thickness of the normal and diseased cartilage, and the inner and outer surfaces, and the subchondral bone. Of course, nearly any surface can be considered either an inner or an outer surface depending on one's point of view.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have considered the cartilage surface when designing the prosthesis in Ateshian et al. as taught by Aouni-Ateshian et al. While Ateshian et al. only refer to the joint surface, one of ordinary skill in the art is aware that this would include both articular cartilage as well as subchondral bone, and it would be obvious to take into account all parts of the joint when designing an anatomically correct implant, as this will increase the accuracy of the design. Furthermore, it would have been obvious to use the images obtained by Ateshian et al. to create a 3D model as taught

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by Aouni-Ateshian et al., and to have then used the model to design the prosthesis. A 3D model will provide a suitable mechanism for visualizing the image data and designing a more accurate prosthesis.

When designing such an implant, it is of course necessary for it to reflect the proportions of the body part being replaced so that it will fit appropriately within the patient. Therefore, at least a portion of the implant would have thickness similar to that of normal articular cartilage adjacent to diseased articular cartilage.

Claims 18-19, 21, 55-58, 60, 66-71, 85-86, 94-152, and 228-256 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ateshian et al. (US 6126690) in view of Aouni-Ateshian et al. (US 6161080) as applied to claims 1, 10, 153, and 190 above, and further in view of Delp et al. (US 5682886) and Paul et al. (US 5320102).

Paul et al. disclose a method of treating a human with diseased cartilage in a joint. Paul et al. teach a method of treating a human with diseased cartilage in a joint (abstract), which method comprises: utilizing an MRI scan to generate a cross-sectional electronic image of said joint (column 4, lines 1-55), wherein said image includes both normal and diseased cartilage (column 10, lines 55-65); and utilizing information from said image to create a geometric model of an area of diseased cartilage (the MR cartilage image is a model, column 4, lines 55-65), wherein said geometric model is used in selecting a treatment of said diseased cartilage (column 11, lines 35-55); electronically evaluating the image of the joint to determine the thickness or biochemical content (column 4, lines 1-10, and column 5, line 65-column 6, line 5); obtaining a three-

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dimensional map (the MR cartilage image is a three-dimensional map, column 4, lines 55-65); determining the margins of the diseased cartilage in relation to the normal cartilage based on the thickness or biochemical contents, allowing for the area of diseased cartilage to be calculated (the MRI scan of the joint allows for the total cartilage surface area to be determined, knowledge of the margins of the diseased area will then allow for a calculation of the total area of the joint containing diseased cartilage, column 10, lines 55-65). Also, estimating the change in thickness of a region of the cartilage over time to determine a change in thickness between a first time and a second time, to determine the amount of degeneration in the cartilage (column 11, lines 5-55); the therapy includes an agent that stimulates repair of diseased tissue (column 11, lines 45-55); the MRI technique obtains a series of two-dimensional views reconstructed to a three-dimensional image (implicit with MR imaging); the MRI technique employs gradient or spin echo (column 4, lines 25-40). Data transmission throughout a computer system is well known in the art, any part of the computer can be considered a "site" or the receiving or transmitting device, and the term "located distant" can refer to any distance.

It would have been obvious to one of ordinary skill in the art, to analyze the degenerative cartilage in the patient and to have determined a therapy based on the cartilage information as taught by Paul et al., in the prosthesis design of Ateshian et al. and Aouni-Ateshian et al., in order to better develop a proper implant.

Delp et al. show a system for joint replacement surgery. The system processes medical image data to build a 3D computer model of the patient's leg, and align, size,

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and place a prosthetic component (column 8, lines 5-31). The three-dimensional geometry of the joint is analyzed to determine the required dimensions and geometry of the prosthesis. A number of points are selected in the 3D surface reconstruction of the joint and prosthesis (column 9, line 19-column 11, line 5). Selecting points in three-dimensional space in order to develop the proper dimensions and geometry of a three-dimensional object would inherently include determining three non-coplanar points. Points would be selected on the different bones of the joint, such as in the case of a knee joint, the lateral or medial femoral condyle (column 7, lines 38-52). A variety of different imaging modalities can be used to obtain the data (column 8, lines 32-61). The biomechanical information, such as the biomechanical axes, is obtained (column 11, lines 49-59) and used when designing the model, as well as anatomical information such as anatomical landmarks (column 11, lines 25-27). The contact surfaces are accounted for as well (column 14, lines 1-42). By utilizing constraints, both static and dynamic alignment are accounted for, in order to ensure that there is equal contact throughout the range of motion and to prevent the ligaments from being too tight in extension. Estimating for normal gait is an obvious modification, as gait is a typical unconstrained movement, and would be accounted for when ensuring equal contact throughout the range of motion.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used a planning system to properly place the prosthesis and aid in the design of the prosthesis of Ateshian et al. and Aouni-Ateshian et al. This



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will provide a more accurate prosthesis by taking into account a variety of other patient specific parameters such as gait.

Claims 20 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ateshian et al. (US 6126690) in view of Aouni-Ateshian et al. (US 6161080), as applied to claims 1 and 10 above, and further in view of George, III et al. (US 6175655).

George, III et al. disclose a method for manipulating 3D MRI data to view internal body structure. George, III et al. teach the use of 3D Euclidean distance values in manipulating the 3D MRI data (table of column 8-column 9 shows a variable used which is Euclidean distance between points).

The Euclidean distance is a well known technique to calculate the distance between two points, and could be used when constructing the 3D model of Ateshian et al. and Aouni-Ateshian et al. in order to accurately construct the 3D model. A variety of techniques and mathematical calculations are used when constructing an accurate 3D model and it would be obvious to one of ordinary skill in the art to use any known techniques for constructing the model as they are suitable equivalents which yield the same end result.

Claims 22 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ateshian et al. (US 6126690) in view of Aouni-Ateshian et al. (US 6161080), as applied to claims 1 and 10 above, and further in view of Goldberg et al. (US 6835377).

Goldberg et al. disclose a method for repair of degenerative cartilage. Goldberg et al. teach that the therapy can comprise osteotomy or an autologous chondrocyte transplantation (it is well known to perform osteotomy, column 1, lines 40-50, also the method used in the invention uses autologous mesenchymal stem cells supported by a three-dimensional scaffold, which is implanted in the body, column 3, lines 1-25).

It would have been obvious to one of ordinary skill in the art, to have implanted a device as taught by Goldberg et al. in place of the prosthesis implanted by Ateshian et al. and Aouni-Ateshian et al. in order to aid in repairing the degenerated cartilage.

### ***Response to Arguments***

Applicant's arguments filed 4/23/10 have been fully considered but they are not persuasive.

In regards to applicant's arguments that the Ateshian '690 patent does not enable the creation of patient-specific implants with MRI or CT scans, examiner respectfully disagrees. First, it should be noted that all of the arguments are merely applicant's own opinions and interpretations of the Ateshian patents. Such opinions are not sufficient to prove that a granted patent is not enabled. Also, applicant argues that the Ateshian patent is not enabled because Ateshian could not have reduced such an invention to practice. However, Ateshian did not have to reduce the invention to practice prior to filing to comply with the enablement requirement (see MPEP 2164.02). The examiner would also point out that the Ateshian et al. '690 reference and the Aouni-Ateshian et al. '080 reference contain different inventive entities. Thus, it is unclear who the author of

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each patent was, and it is difficult to compare the words in the references exactly as if the same person had written them. Doing so requires a great deal of assumption and interpretation, rather than fact.

Applicant relies upon statements made in the later '080 reference in which the inventors state that it "may be possible" to obtain geometric data needed for the model directly from patients. However, in the following sentences, the inventors then go on to state that several investigators "have" reconstructed cartilage topography and thickness from MR images, and that once the patient joint geometry is obtained, a patient specific model can be constructed. Thus, these sentences indicate that this feature had already been accomplished in the field, and was known to those of ordinary skill in the art. In addition, as indicated above, it was not necessary for Ateshian to reduce the invention to practice in order to meet the enablement requirement. The fact that the patent was issued is evidence in itself that all enablement requirements were met. Every patent is presumed valid, see MPEP 716.07. Furthermore, one skilled in the art would have known how to implement the features of the references.

In regards to applicant's arguments that the collection of references does not disclose obtaining image data of a joint and generating a patient-specific device having an articular surface that is based on the information in the image data, the examiner believes that this limitation is taught by the Ateshian et al. '069 reference. Ateshian et al. '069 discloses obtaining images of the joint and designing a prosthesis based on the image data as indicated in the rejection above.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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